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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/926,661	02/28/2002	Masatoshi Chiba	P21749	5687

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GREENBLUM & BERNSTEIN, P.L.C.
1950 ROLAND CLARKE PLACE
RESTON, VA 20191

EXAMINER

KOLKER, DANIEL E

ART UNIT PAPER NUMBER

1649

DATE MAILED: 02/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/926,661

Applicant(s)

CHIBA, MASATOSHI

Examiner

Daniel Kolker

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 January 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,4,6-16 and 22-28 is/are pending in the application.
- 4a) Of the above claim(s) 22-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,4 and 6-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1,3,4,6-16 and 22-28 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>1/18/06</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's remarks, amendments, and machine translation of a priority document, each filed 18 January 2006, have been entered. Claims 2, 5, and 17 – 21 are canceled; claims 22 – 28 are new. Claims 1, 3 – 4, 6 – 16, and 22 – 28 are pending.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Election/Restrictions

3. Newly submitted claims 22 – 28 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the claims are drawn to methods of making products of different scope, which are further patentably distinct from the originally-elected product.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 22 – 28 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

4. Claims 22 – 28 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 28 July 2005.

5. This application contains claims 22 – 28 drawn to an invention nonelected with traverse in the response filed 28 July 2005. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

6. Claims 1, 3 – 4, and 6 – 16 are under examination.

Withdrawn Rejections and Objections

The following rejections made in the previous office action are withdrawn:

- 1) The rejection under 35 USC § 102 for anticipation by Tanaka. Applicant's amendments are sufficient to overcome the rejection.

Rejections and Objections Necessitated by Amendment

Claim Objections

7. Claims 1 and 3 are objected to because of the following informalities: they recite non-elected subject matter. Applicant has amended the claims to recite multiple stabilizing agents. In the response filed 28 July 2005, applicant elected arginine as the stabilizing agent. The other agents (lysine, histidine) added to claims 1 and 3 in the amendments filed 18 January 2006 are non-elected. Appropriate correction is required.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 11 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 11 depends from claim 2, but claim 2 is canceled.

Maintained Rejections and Objections

Information Disclosure Statement

9. The examiner has considered the previously-submitted documents for which no translation has been provided to the extent possible by one who is totally unfamiliar with the language in which they are written. For example, Japan 63-22526, cited on IDS, contains no English sentences; even the figures are in Japanese.

On p. 11 of the remarks, applicant argues that English language translations of abstracts are sufficient as concise explanations of the relevance of foreign-language documents. While that is of course true, many of the Japanese references do not have abstracts in English. In the previous office action, the examiner indicated that several of the translations listed on the IDS were not in the case. These have since been received and considered.

Claim Objections

10. Claims 4 and 6 are objected to because of the following informalities: they recite non-elected subject matter. Appropriate correction is required.

In the remarks filed 18 January 2006, applicant indicated that rejoinder of non-elected species is appropriate upon allowance of a generic claim. However, applicant's arguments are moot as no claims are allowable for the reasons set for the herein.

Claim Rejections - 35 USC §§ 102 and 103

11. Claims 1, 3 – 4, 6 – 9, and 12 – 15 stand rejected under 35 U.S.C. 102(b) as being anticipated by Nakamura et al. (European Patent Application 0456188A1, published 13 November 1991, cited on IDS filed 27 March 2002). This rejection is maintained for the reasons made of record in the previous office action and explained in further detail herein.

Briefly, Nakamura teaches the same product that applicant is claiming herein and explicitly teaches the addition of arginine as a stabilizing agent (see column 9 lines 52 – 58). Applicant is referred to the previous office action for a more detailed description of how Nakamura teaches every limitation of the rejected claims.

Applicant argues, in the paragraph spanning pp. 15 – 16 of the remarks, that the prior art does not teach how to make the claimed product. The examiner disagrees. In the interest of brevity, applicant is again referred to the previous office action. The examiner has set forth a prima facie case that Nakamura teaches every element of the claimed invention. Applicant has not provided any evidence that the product now-claimed is any different from that taught in 1991, nor has applicant indicated which of the specific elements in claims 1, 3 – 4, 6 – 9, or 12 – 15 the reference fails to teach. Every limitation of these claims is fully taught by the reference, and thus the claims are anticipated.

Applicant also argues that since the explicit combination recited in the claims is not directly taught, the reference cannot be considered to fully anticipate the claimed invention. Applicant is directed to MPEP § 2131.02, particularly the sections entitled "A species will always anticipate a genus" and "A reference that clearly named the claimed species anticipates the claim no matter how many other species are named". In this case, claims 1 and 3 have been amended to recite a very small number of stabilizing agents (arginine, lysine, histidine, glutamine, proline, glutamic acid, aspartic acid, salts thereof). The prior art reference of Nakamura very clearly teaches the elected stabilizing agent arginine. See column 9, beginning at line 52, which states "The... agents may contain other additives such as stabilizers... and examples thereof includes for example sugars such as mannitol and glucose, amino acids such as glycine, alanine lysine and arginine". The very next paragraph teaches that the liquid

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preparations are to be freeze- or vacuum-dried; lyophilization is a form of vacuum drying at freezing temperatures. Thus the reference very clearly teaches the invention. The examiner notes that Nakamura did not simply name amino acids in a generic manner, but very explicitly named arginine as a suitable stabilizing agent. Thus the reference anticipates claims 1, 3, 4, and 6.

Claims 7, and 12 – 14 are drawn to different components of the composition that is lyophilized. Again, in the interest of brevity the examiner directs applicant to the previous office action which lists the precise location of each of these in the Nakamura reference. The logic explained above also applies here. Since the prior art teaches each species, it does not matter how many other species are listed. Claims 8 – 9 are drawn to certain inherent properties and thus the reference anticipates these claims. The examples in column 14 clearly state that vials are used for lyophilization, thus meeting the limitations of claim 15.

12. Claims 1 and 16 are further rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Nakamura. This rejection is maintained for the reasons made of record in the previous office action and explained further herein.

After setting forth a prima facie case of anticipation or obviousness, the burden shifts to applicant to rebut the case. However applicant provided no evidence that the claimed product was distinguishable from the prior art product and thus the rejections stands for the reasons of record.

13. Claims 1, 3, 4, and 6 – 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nakamura (European Patent Application 0456188A1), in view of Tanaka et al. (WO 97/02832, published 30 January 1997), as evidenced by Tanaka et al. (U.S. Patent Application Publication 2001/0051604, published 13 December 2001, cited by applicant on IDS filed 27 February 2004). This rejection is maintained for the reasons of record.

The reasons why claims 1, 3, 4, 6 – 9 and 12 – 16 are anticipated by, or in the alternative obvious over, Nakamura are set forth in the rejection under 35 USC § 102(b) above. Briefly, Nakamura teaches lyophilized preparations comprising HGF and stabilizers as claimed by applicant. However, Nakamura does not teach pH of the solution before lyophilization in the range of 5 to 6.5.

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Tanaka teaches preparation of lyophilized HGF wherein the pH of the solution before lyophilization is between 5.0 and 6.5, and further comprising stabilizing agents including amino acids (see page 2, paragraph 0017), and buffering agents to keep the pH in the desired range. Specifically, Tanaka teaches buffers comprising citrate, where in the pH is between 5.0 to 6.0 (see page 2, paragraph 0018). Tanaka teaches that keeping the pH between 5.0 and 6.0 is advantageous, as HGF shows increased solubility at this pH. Thus the teachings of Tanaka meet the limitations of claims 10 and 11. Tanaka also teaches that lyophilization according to their disclosed method is sufficient to prevent aggregate formation (see page 1, paragraph 0006), meeting the limitations of claim 16. However Tanaka does not teach compositions comprising arginine recited in claims 1, 3, 4, and 6.

It would have been prima facie obvious to one of ordinary skill in the art to make the lyophilized preparation of Nakamura using the buffer with pH 5.0 – 6.5 as taught by Tanaka, with a reasonable expectation of success. Tanaka teaches that the lower pH range is advantageous, as HGF is more soluble in the more acidic environment. Therefore one of ordinary skill in the art would be able to make the preparation faster, as it would take less time for the HGF to dissolve. It would be reasonable to expect success, as both references are drawn to the same subject matter, namely preparation of lyophilized HGF and use of multiple buffer systems is within the skill of the ordinary artisan.

Applicant did not argue, or present evidence, that there was an improper determination of obviousness in the previous office action. While the amendments to claim 1 is sufficient to overcome the rejection of Tanaka under 35 USC 102, because the teachings of Tanaka are also drawn to lyophilized preparations comprising HGF, they are relevant to applicant's invention. Thus the rejection stands for the reasons of record.

Conclusion

14. No claim is allowed.

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

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MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel Kolker whose telephone number is (571) 272-3181. The examiner can normally be reached on Mon - Fri 8:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Daniel E. Kolker, Ph.D.

February 15, 2006



ROBERT C. HAYES, PH.D.
PATENT EXAMINER